

# Exhibit CC

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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MITSUBISHI TANABE PHARMA CORPORATION, et al. CIVIL ACTION NUMBER:  
17-5005

Plaintiffs, ORAL ARGUMENT VIA  
TELECONFERENCE

v.

AUROBINDO PHARMA USA, INC.,  
et al.,

Defendants.

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Tuesday, April 14, 2020  
Commencing at 2:00 p.m.

B E F O R E: THE HONORABLE JOEL SCHNEIDER,  
UNITED STATES MAGISTRATE JUDGE

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1 THE COURT: Okay. Let's go on the record now.  
2 We're on the record in the matter of Mitsubishi, Docket No.  
3 17-5005. I suppose everyone wants to enter their appearance  
4 on the docket, so why don't we start with plaintiffs' counsel,  
5 and then we will go to defense counsel.

6 MR. BATON: Good afternoon, Your Honor, this is Bill  
7 Baton of Saul Ewing Arnstein & Lehr, New Jersey counsel for  
8 plaintiff. I did try to coordinate with all parties to send  
9 around a service -- a list of all participants for each of the  
10 parties, and hopefully, you got that. I also sent it to  
11 Ms. Eckert as well. I'll let my co-counsel introduce  
12 themselves as well.

13 MS. JAMES: Good afternoon, Your Honor, this is  
14 Colleen James of the Quinn Emanuel firm for plaintiff. Also  
15 with me on the line are my colleagues also from Quinn Emanuel,  
16 Ray Nimrod, Catherine Mattes, and Brian Forsatz. Thank you,  
17 Your Honor.

18 THE COURT: Thank you.

19 All right. There's also defense counsel on the  
20 phone. Why don't we start by whoever is going to be the lead  
21 in terms of oral argument and then everybody can say their  
22 name.

23 MS. MAZZOCHI: Thank you, Your Honor. Good  
24 afternoon, this is Deanne Mazzochi, D-E-A-N-N-E, Mazzochi,  
25 M-A-Z-Z-O-C-H-I, for the Lupin defendants. I'm also joined by

1 my colleague Matt Anderson and local counsel Melissa Flax.

2 MS. FLAX: Good afternoon, Your Honor. Melissa Flax  
3 from Carella Byrne on behalf of Lupin defendants.

4 THE COURT: All right, defendants, if you want to  
5 enter your appearance, feel free to. If you want to wait,  
6 that's fine with the Court as well.

7 MR. ABRAHAM: Good afternoon, Your Honor, this is  
8 Eric Abraham from Hill Wallack in Princeton. I represent  
9 Sandoz. I'm joined on the call by Mark Remus and Joshua James  
10 from Brinks Gilson also on behalf of Sandoz.

11 MS. HAND: Good afternoon, Your Honor, this is  
12 Rebecca Hand from Cosner Youngelson, local counsel for  
13 Aurobindo. On the line with me is Marc Youngelson also from  
14 Cosner Youngelson and James Neilon and Steve Moore from  
15 Withers Bergman.

16 MR. KELLY: Good afternoon, Your Honor, this is Sean  
17 Kelly of the Saiber Law Firm, local counsel for Zydus, and  
18 with me on the call are Hershy Stern and Trevor Welch of the  
19 firm of Kasowitz Benson Torres.

20 MR. COHEN: Good afternoon, Your Honor, this is  
21 Jeffrey Cohen from the law firm of Flaster Greenberg. I'm  
22 local counsel for Laurus Labs, and with me on the phone is  
23 Joseph Kim from the law firm of Sterne Kessler Goldstein &  
24 Fox.

25 MR. RICHTER: Good afternoon, Your Honor, James

1 Richter of Midlge Richter on behalf of MSN and with me on the  
2 line is Jovial Wong and Sharon Lynn, both from Winston &  
3 Strawn.

4 THE COURT: Okay. Why don't we do this, then.  
5 There's probably other people on the phone, but whoever's  
6 going to talk, do announce your name for the benefit of the  
7 court reporter, so she can take the transcript down.

8 We're here for oral argument on plaintiffs'  
9 application submitted on March 20, 2020, Docket No. 278. The  
10 Court has read all the submissions of the parties. I think it  
11 understands the issues, but anticipates that this oral  
12 argument will be very helpful.

13 I want to start by just setting a couple of ground  
14 rules for the oral argument. This case is a little bit  
15 different than most of my cases. This is, in my view, an  
16 exceedingly complicated issue that involves a detailed  
17 comparison of the two subject expert reports and the lengthy  
18 contentions that were filed earlier in the case.

19 We're all proceeding under a little bit of a handicap  
20 these days because of the coronavirus situation. Ordinarily,  
21 we would hold this argument in person, but clearly, because of  
22 the current circumstances, we have to do this by phone, which  
23 is not ideal, but it's certainly better than nothing.

24 The Court wants to advise you at the outset of this  
25 argument that I will reserve decision today. I don't

1 ordinarily do that, I like to rule on the record when there's  
2 argument, but these issues, in my view, are too complicated to  
3 jump into the same day as oral argument.

4           What I anticipate is either after we digest the  
5 argument today and the Court goes back and does a little bit  
6 of homework, I'm either going to schedule a second oral  
7 argument to fine-tune some questions the Court has, or I'll  
8 issue an oral opinion on the record with an order to be  
9 followed.

10           Like you, our office is closed, we're working  
11 remotely. So it's a little bit more cumbersome for the Court  
12 to write a lengthy opinion, but I can certainly read a  
13 decision into the record.

14           I'm aware of the scheduling deadlines in the case.  
15 All present scheduling deadlines shall remain in place. The  
16 final pretrial conference I know is scheduled on June 1.  
17 Trial is scheduled on June 22nd, and as far as I'm concerned,  
18 unless someone says the trial is going to be delayed or  
19 postponed, it's full speed ahead.

20           The way I'd like to proceed is, it appears to the  
21 Court and we'll clarify this, that there were three general  
22 subject areas of dispute, and what I'd like to do is deal with  
23 one at a time and hear the argument of plaintiffs, since  
24 they're the moving party, and exhaust the argument on the one  
25 point and then move on to the second and third point.



1 I don't want to waste time on issues that are not  
2 material to the Court's decision. So there are one or two  
3 points that I just want to make clear up front so you don't  
4 have to waste your time arguing about it.

5 The first point is that the Court rules and finds  
6 that plaintiffs' application is ripe for decision and the  
7 Court will not hold off on ruling on the dispute for a motion  
8 in limine or an objection at trial. So that argument is  
9 rejected.

10 The second point is, and this was alluded to in  
11 plaintiffs' argument, the Court does not accept the argument  
12 that defendants, in essence, admitted the subject expert  
13 reports violated the local patent rules because they offered  
14 compromises in the context of the parties' meet-and-confer  
15 session. So there's no need to raise that point.

16 And the third point is, the Court is skeptical of the  
17 argument, if it's made, that plaintiff waited too long to  
18 raise these alleged deficiencies. In the Court's view, the  
19 burden is on the defendant to comply with the local rules, and  
20 in the absence of any evidence of sandbagging or bad faith,  
21 the Court is not going to put the burden on plaintiff to point  
22 out to the defendant the deficiencies in their contentions.  
23 And the Court has seen no evidence on either side of any bad  
24 faith or shenanigans.

25 So those are the three points that the Court has

1 already concluded on. I wanted to make that clear, so we  
2 don't have to waste time on those arguments.

3 I'm familiar with the issues in dispute. We're  
4 dealing with plaintiffs' application to strike portions of the  
5 expert report of Dr. Eckhardt and Dr. Cockcroft that were  
6 served on or about February 7, 2020.

7 The essence of plaintiffs' argument is that portions  
8 of those expert reports set forth new invalidity theories and  
9 new cited references that violate the strictures of local  
10 Rules 3.3 and 3.7.

11 The Court is aware that the defendants' joint  
12 invalidity contentions were served on March 30, 2018.  
13 Plaintiff responded on June 29th, 2018. Sandoz's contentions  
14 were filed on March 30, 2018. They supplemented those  
15 contentions, Sandoz did on September 19, 2018. On  
16 November 12, 2018, plaintiff responded to Sandoz's  
17 supplemental contention, and as the Court noted, the expert  
18 reports at issue were served on February 7, 2020.

19 Plaintiffs' application was filed on March 20, 2020,  
20 about a month-and-a-half later, and we know that the trial  
21 date is June 22nd, 2020.

22 I'd just like confirmation from the parties so we're  
23 all on the same page. I know there's subsets of arguments for  
24 the three general areas, but it appears to the Court that the  
25 three general objections are as follows: As to obviousness,

1 plaintiff is contesting Paragraphs 299, 365 of the Eckhardt  
2 report. As to anticipation in 326, Paragraphs 253 to 298 and  
3 the third general argument is the Section 112 invalidity  
4 argument, Paragraphs 95 to 142 of Cockcroft's report.

5 Counsel, with that background, does the Court have it  
6 correct at least as of now?

7 MR. BATON: Your Honor, this is Bill Baton, New  
8 Jersey counsel for plaintiffs. Just one slight correction.  
9 Our initial letter was filed on March 2nd, 2020, our reply was  
10 March 24. We were planning to have me speak a little bit with  
11 Your Honor about local patent rule issues and my colleague  
12 Colleen James from Quinn Emanuel was going to address the more  
13 substantive issues with respect to your queries just now. So  
14 I'll let Ms. James answer that and then we can continue.

15 THE COURT: Mr. Baton, if you don't mind, the Court  
16 is very familiar with the local patent rules. You've probably  
17 read my opinions on the local patent rules. I know all about  
18 Rule 15, I know all about Sanders in the patent rules.  
19 They're not the same as Rule 15.

20 So I don't mean to take the wind out of your sails,  
21 but would there be any objection if we just get to the crux of  
22 these issues rather than the background that the Court is  
23 already familiar with.

24 MR. BATON: Sure, Your Honor. This is Bill Baton  
25 again. I obviously will defer to the Court's wishes on how to

1 structure the argument. The only thing I would ask the  
2 Court's indulgence would be, if you are asking a question of  
3 my colleague, your specific questions and it somehow may touch  
4 upon an argument that we have that's grounded in local patent  
5 rules, that you allow me to, you know, pinch hit for that, so  
6 to speak, and at least cut the background.

7 THE COURT: Absolutely. No problem at all.

8 MR. BATON: Thank you, Your Honor.

9 THE COURT: I just -- let's start with -- just so I  
10 at least have the three general disputes correct, the  
11 obviousness argument, the anticipation argument, and the  
12 Section 112 argument.

13 MS. JAMES: Your Honor, this is Colleen James and for  
14 plaintiffs we agree that those are the three main categories  
15 at issue for discussion today.

16 MS. MAZZOCHI: And this is Ms. Mazzochi. That's true  
17 for defendants as well.

18 THE COURT: Okay. So what I'd like to do is start  
19 with one at a time, hear from the plaintiffs, they're the  
20 moving party, we'll exhaust the argument, and then we'll move  
21 on to the next argument. What I'd like to do is, I'd like to  
22 save what I think is the most complex issue, as far as the  
23 Court is concerned, is the obviousness issue. I'd like to  
24 save that for last, and start with the Section 112 invalidity  
25 argument.

1 I want to start with what I perceive as more the  
2 straightforward issue and then get to the more complicated  
3 issue.

4 So if you'll indulge the Court. Ms. James, if you're  
5 going to argue, let's start with the Section 112 invalidity  
6 argument. Tell me why the Court -- it appears to the Court --  
7 are you seeking to strike Paragraphs 95 to 142, the entirety  
8 of it?

9 MS. JAMES: Yes, Your Honor. In -- when we look at  
10 the 112 bucket, there's three different subsections that are  
11 associated with Section 112, written description, enablement  
12 and indefiniteness, and if it's okay with Your Honor, I will  
13 take each of those in turn.

14 THE COURT: Perfect. No problem.

15 MS. JAMES: Because we understand, Your Honor, this  
16 is complicated. It was complicated for us, as well, to sort  
17 of piece this all together and figure it out. So I've  
18 endeavored to try to simplify this as much as possible for the  
19 Court for our discussions today.

20 THE COURT: Well, that would be helpful since you do  
21 this for a living, I don't.

22 MS. JAMES: So we'll start out really simple and I'll  
23 lay the foundation and we could expand the discussion as we  
24 continue our conversation. But the basic premise, Your Honor,  
25 is that when we looked at the defendants' contentions that

1 were served in 2018, we believe that we had the right to rely  
2 on the arguments that were disclosed in those contentions.  
3 And we proceeded throughout this entire case, all through fact  
4 discoveries, the *Markman* hearing, and to the beginning of  
5 expert discovery relying on those contentions.

6           It was surprising to us when we received  
7 Dr. Cockcroft's expert report to learn that there were new  
8 arguments that were never disclosed in the joint contentions  
9 or in the Sandoz contentions. One of those arguments was  
10 written description. In the joint contentions, the defendants  
11 did have an argument that Claim 1 of the '582 Patent did not  
12 satisfy the written description requirement, but the  
13 contentions were silent with respect to Claims 3 and 4 of the  
14 '582 Patent and any alleged deficiencies for written  
15 description.

16           The claim that plaintiffs are asserting now in the  
17 case are Claims 3 and 4. Claim 1 is no longer being asserted  
18 and is, therefore, no longer relevant. And because the joint  
19 contentions do not contain any disclosures or advance warning  
20 of a written description argument for Claims 3 and 4 of the  
21 '582 Patent, we believe those sections should be removed from  
22 Dr. Cockcroft's expert report.

23           THE COURT: Okay. So I appreciate that and I think  
24 it's very helpful to break up the argument into the three  
25 sections -- Section 112 argument into the three subsections.

1 Why don't we -- if you're done with your argument as to the  
2 written description issue, why don't we hear what the  
3 defendant has to say on written description, then we'll go to  
4 enablement and indefiniteness. But I don't want to cut you  
5 off if you have something else to say on written description,  
6 let's hear it.

7 MS. JAMES: No, Your Honor. I would like to reserve  
8 my right to reply --

9 THE COURT: Of course.

10 MS. JAMES: -- to the defendants' argument. But that  
11 is basically, simply put, the basic essence of our argument  
12 and I don't need to expound more and waste the Court's time.

13 THE COURT: So let's hear from the defendant. And  
14 what would be very, very, very helpful for the Court,  
15 Defendant, is plaintiff is saying black and white, couldn't be  
16 clearer. Claim 3 and 4 are not mentioned in the joint  
17 contention, not disclosed.

18 Can you point me to where I could look at to find the  
19 disclosure?

20 MS. MAZZOCHI: Thank you, Your Honor. I would start  
21 with our -- with the defendants' joint contentions at Page 46,  
22 and one thing that I would like to give as background, Your  
23 Honor, is that Claim 1 of the -- of the asserted claims in the  
24 '582 Patent, for example, that claim -- the term in the claim  
25 that the parties are really disputing is the language, a

1 crystalline form and as it applies to hemihydrate.

2 That hemihydrate term, likewise -- you know, likewise  
3 is incorporated into Claims 3 and 4, because Claims 3 and 4  
4 are dependent on Claim 1. So that's why all of the arguments  
5 pertaining to Claim 1 equally transfer over to Claims 3 and 4.

6 And, in fact, if you look at Page 46 of our  
7 contention, when we started the analysis of Section 112  
8 invalidity, you know, we noted that this was based on certain,  
9 you know, contentions raised by the plaintiff. We do say the  
10 defendants' belief is that the asserted claims, and that  
11 includes Claims 1, Claim 3, Claim 4, the plaintiffs were  
12 asserting other claims at that time, that the invalid for  
13 indefiniteness for failure to set aside a written description  
14 requirement and enablement requirements of Section 112 of the  
15 Patent Act.

16 So I disagree that we never put plaintiffs on notice  
17 that we believed all of these defenses applied to all of the  
18 claims that they were asserting.

19 THE COURT: So it sounds to me like you're not  
20 disputing that Claims 3 and 4 were not specifically mentioned,  
21 but it should have been inferred from the language that you  
22 used that it was included. Is that what you're saying?

23 MS. MAZZOCHI: No. I was saying that the whole  
24 theory under Claim 1 and we start that explanation off on  
25 Page 47 of the contentions. When we explain that Claim 1



1 lacks sufficient written description, our rationale for why  
2 this is so, is because the specification does not indicate the  
3 other -- all of the crystalline forms of canagliflozin  
4 hemihydrate that the plaintiffs had contended could fall  
5 within the scope of their claims and that the specification  
6 doesn't give a description beyond one particular type. And we  
7 specifically note why the x-ray analysis, which is one of the  
8 things that's incorporated into the dependent claim as well  
9 doesn't support the full written description scope.

10 So I would not agree that we didn't -- that all of  
11 the defendants did not take that position. And then I don't  
12 know if Sandoz also wishes to jump in, but Sandoz's invalidity  
13 contentions, likewise, you know, applied their analysis to all  
14 of the claims.

15 So, for example, in the Sandoz supplemental  
16 contentions, I believe this is at Page 35, they specifically  
17 said Claims 1 and 3 through 5 of the '202 Patent are invalid  
18 for lack of written description.

19 You know, so I don't think that there was ever any  
20 intent to limit the scope of the written description analyses  
21 to just Claim 1, whether we're talking about the '582 Patent  
22 or the '202 Patent.

23 THE COURT: Am I correct, Ms. Mazzochi, that your  
24 firm didn't prepare these contentions, that was your  
25 predecessor firm?

1 MS. MAZZOCHI: That's correct, Your Honor.

2 THE COURT: Okay. And correct me if I'm wrong, but  
3 as far as I could see, Sandoz's contentions are not at issue  
4 in this dispute. Plaintiff is not seeking to strike any of  
5 Sandoz's contentions. We're just dealing with these two  
6 expert reports, right?

7 MS. MAZZOCHI: Correct. But the expert reports, Your  
8 Honor -- again, this is Ms. Mazzochi. The expert reports are  
9 being submitted on behalf of all of the defendants. So Sandoz  
10 didn't -- on the invalidity issues, the defendant submitted  
11 just one expert report from Dr. Cockcroft on all of the 112  
12 issues. And likewise, the defendants jointly issued one  
13 single expert report from Dr. Eckhardt, with the expectation  
14 that the Court would not tolerate hearing from multiple  
15 experts on behalf of multiple defendants on the same issue at  
16 trial.

17 THE COURT: And maybe this gets into Mr. Baton's  
18 argument. Do you believe that even though you -- not you, the  
19 contentions does not specifically mention 3 and 4, that that  
20 complies with the language in the local patent rules?

21 MS. MAZZOCHI: We think it does, Your Honor, because  
22 the issue that is in dispute centers around Claim 1. Claim 1  
23 is incorporated by reference in the '582 Patent into Claims 3  
24 and 4. At the time we prepared the contentions, the plaintiff  
25 certainly had not surrendered Claim 1. They actually only

1 surrendered Claim 1, you know, within the last few weeks. So,  
2 you know, I don't think that was even on our radar screen.

3 And when I read the local rules, it just asks you --  
4 under 3.3(b), it just says to raise grounds of invalidity  
5 based on 101, 112(b) or enablement or written description,  
6 including, you know, any of the asserted claims including a  
7 detailed explanation of the basis for the asserted grounds.

8 Well, the grounds that Dr. Cockcroft has articulated,  
9 whether you apply them to Claim 1, to Claim 3, to Claim 4,  
10 it's the same rationale, and it's the same rationale that was  
11 already disclosed in the contentions.

12 THE COURT: Okay. But there's no legitimate dispute  
13 that it would have been crystal clear -- I'm looking at  
14 Page 46, if instead of saying Claim 1 of the '582 Patent, it  
15 would have said Claim 1, 3, and 4 of the '582 Patent. That's  
16 not in dispute, is it?

17 MS. MAZZOCHI: But when you look at how -- sorry,  
18 Your Honor, this is Ms. Mazzochi. But when you look at the  
19 very beginning, when we defined what we meant by the phrase  
20 Asserted Claims, capital A Asserted, capital C Claims, and  
21 this is on Page 2, we specifically stated that the Asserted  
22 Claims encompassed Claims 1, 3 to 4, and 6 to 7 of the '582  
23 Patent, and Claims 1 and 3 to 5 of the '202 Patent.

24 THE COURT: Okay. Let's hear from the reply of  
25 plaintiff and then we'll move on to the enablement.

1 MS. JAMES: Thank you, Your Honor. Again, this is  
2 Colleen James. And I think that what we just heard is  
3 precisely -- it precisely shows the problem.

4 We, as plaintiffs reading the contentions, took the  
5 headings that we see starting on Page 46 at face value. The  
6 headings don't say the Asserted Claims, the headings say  
7 Claim 1 of the '582 Patent is indefinite.

8 Then when we go further into the joint contentions,  
9 starting on Page 52, there's another heading that says,  
10 Invalidity of Claims 3 to 4 and 6 to 7 of the '582 Patent.

11 So it seems -- seemed to us when we were reading  
12 this, that when the defendants wanted to specifically make an  
13 argument for a specific claim, like 304, they broke that out  
14 into a separate section. There is no separate section for a  
15 written description argument for Claims 3 and 4, unlike there  
16 is for other types of arguments for Claim 3 and 4.

17 So it was reasonable, we believe, for us, to rely on  
18 the contentions the way they were written, and not expect a  
19 written description argument on Claims 3 and 4, because it's  
20 just not in there, it's not included. And for us to have to  
21 put all these pieces together that the Asserted Claims really  
22 means that Claims 3 and 4 apply to the written description  
23 argument for Claim 1 when those claims are not even mentioned  
24 in that section but in other sections Claims 3 and 4 are  
25 particularly broken out, that seems like a lot of guessing

1 that we have to do and that, to us, we respectfully submit,  
2 does not seem to fit within the spirit of the local rules.

3 THE COURT: Okay. Question for you. I'm not ruling  
4 now, I told you, I'm reserving decision. Hypothetically, if  
5 the Court agrees with the plaintiff, would it mean in your  
6 judgment that the entirety of Paragraph 95 to 142 would be  
7 stricken or are there particular paragraphs that only pertain  
8 to written description?

9 Suppose the Court accepts the written description  
10 argument but rejects the enablement and indefiniteness  
11 argument. What paragraphs are we talking about?

12 MS. JAMES: Turning to the Cockcroft report, on  
13 Page 32, Section A, is where the written description argument  
14 begins for Claim 1, 3, and 4. As he said, Claim 1 is no  
15 longer being asserted, so that part of the report is no longer  
16 relevant. And then Claims 3 and 4 are in this section for  
17 written description and that would go through to Page 42,  
18 Paragraph 114.

19 THE COURT: Okay.

20 MS. MAZZOCHI: Your Honor, this is Ms. Mazzochi  
21 again. Just one clarification, Your Honor. I do note there  
22 are Paragraphs 104 through 110 that seem to be more related to  
23 enablement.

24 THE COURT: Okay. All right. Let's move on to  
25 enablement.

1 MS. MAZZOCHI: Your Honor, this is Ms. Mazzochi. If  
2 I can raise two points. I apologize, I just don't want to  
3 lose this train of thought.

4 First, Your Honor, the fact that the plaintiffs are  
5 choosing to not assert Claim 1 does not mean that  
6 Dr. Cockcroft can't offer those opinions, because the  
7 defendants had declaratory judgment counterclaims to  
8 invalidate Claim 1 irrespective of what plaintiffs do or don't  
9 do. So the fact that plaintiffs may not wish to defend  
10 Claim 1 doesn't mean that we don't have the ability to  
11 invalidate it at trial. So I just wanted to make that part  
12 clear.

13 And then additionally, I did want to note for Your  
14 Honor that while plaintiffs' counsel indicated that they had  
15 no clue that anything that was going to be discussed for Claim  
16 -- for the other claim, such as Claim 3, we specifically say  
17 in our contentions in the Claim 3 section at the top of  
18 Page 54: Defendants herein incorporate by reference  
19 Section 2(b)(2), which sets forth the invalidity analysis for  
20 crystalline forms of canagliflozin hemihydrate, Claim 1 of the  
21 '582 Patent.

22 So in addition to the asserted claims, we also  
23 reiterated that we were incorporating this by reference, and  
24 this is not unusual when we have a scenario of independent  
25 claims followed by dependent claims, is that we've already

1 done the analysis for the independent claim, it applies to the  
2 dependent claims and then usually we spend more time on the  
3 dependent claims focusing on the language that is new as  
4 opposed to repeating what was already done.

5 THE COURT: Okay. Time to move on to enablement.  
6 Ms. James, let's hear from you, and are we only talking about  
7 Paragraphs 104 to 110?

8 MS. JAMES: Let me double-check that, Your Honor.  
9 That's correct, Your Honor.

10 THE COURT: Okay. Let's hear your argument.

11 MS. JAMES: Your Honor, in the joint contentions, the  
12 defendants had made an enablement argument. They made the  
13 argument in the joint contentions that following the  
14 instructions in the patents-in-suit in the specifications, a  
15 person of ordinary skill in the art could not make all of the  
16 forms of canagliflozin hemihydrate that were claimed.

17 When we received Dr. Cockcroft's report, however,  
18 there was a new enablement argument, a different one. It  
19 seemed that the defendants abandoned the argument they had in  
20 their contentions and replaced it with an argument that if you  
21 practice the process of Example 1, that it teaches you to make  
22 canagliflozin hemihydrate, you wouldn't get any form of  
23 canagliflozin hemihydrate. So that's a different argument.  
24 It's nuanced but it's different. They went from arguing the  
25 patent doesn't enable one of ordinary skill in the art to make

1 all forms of canagliflozin hemihydrate, to the patent doesn't  
2 enable a person of ordinary skill in the art to make any  
3 canagliflozin hemihydrate.

4 We were surprised to see that in Dr. Cockcroft's  
5 expert report and not only did they make this new argument,  
6 they -- they had an expert who conducted testing to reproduce  
7 Example 1 and relied -- and Dr. Cockcroft relies on that  
8 expert testing to argue that the patent is not enabled to make  
9 any canagliflozin hemihydrate.

10 So this is a perfect example of why the rules require  
11 defendants to put forth their invalidity contentions as early  
12 as possible.

13 When we received Dr. Cockcroft's report, we only had  
14 four weeks. If we would have known a year before or in 2018  
15 or somewhere along the way that defendants were going to argue  
16 this, we would have had the opportunity to do our own testing,  
17 for example, or approach the case in a different way.

18 But this argument, which is totally new, is something  
19 that we had to respond to within four weeks and couldn't  
20 respond to in perhaps the way we might have decided to if we  
21 had known about it earlier.

22 But this new argument is nowhere disclosed in the  
23 joint contentions or in Sandoz's contentions.

24 THE COURT: Can you just go back and highlight the  
25 nuance that you're talking about again? I want to make sure I



1 catch it.

2 MS. JAMES: Of course, Your Honor.

3 Claim 1 of the '582 Patent claims crystalline forms  
4 of canagliflozin, in particular the hemihydrate crystalline  
5 form of canagliflozin. Initially, defendants were arguing  
6 that if that claim covers more than one form of the  
7 hemihydrate crystalline material of canagliflozin, the patent  
8 didn't allow you to make all the forms that could be covered.

9 Does that make sense so far, Your Honor?

10 THE COURT: Yes.

11 MS. JAMES: They didn't make that argument in  
12 Dr. Cockcroft's report. Instead, they argued that if a  
13 scientist took the recipe of Example 1 to make canagliflozin  
14 hemihydrate, it wouldn't work at all, you wouldn't even make a  
15 compound, which was very surprising to us, because -- so as  
16 far as we're concerned, if you follow the instructions in the  
17 patent, you will make canagliflozin hemihydrate, the patent is  
18 enabled to make that.

19 Does that --

20 THE COURT: I got it.

21 MS. JAMES: Thank you, Your Honor.

22 THE COURT: I got it. Okay. Let's hear from  
23 defendant.

24 MS. MAZZOCHI: Thank you, Your Honor. This is  
25 Ms. Mazzochi again.

1           When it comes to enablement, the plaintiffs only  
2 included two patent examples: Example 1 and Example 2. The  
3 argument that they had been making as to why their patent  
4 should survive, but the prior art patent that also talked  
5 about canagliflozin and hydrates and solvates should die, is  
6 because they had a recipe that lets you make the hemihydrate  
7 and the prior art did not.

8           What we then did, because the Wands factors, the  
9 enablement factors, one of the factors is the predictability  
10 or unpredictability of the art and one of the other factors is  
11 the presence or absence of working examples.

12           We knew, and the plaintiff did not dispute, and, you  
13 know, we issued discovery requests on this, tell us how the  
14 seeds were made and the plaintiff admitted they don't know how  
15 the seeds in Example 2 were made. So Example 2 on its face is  
16 a failure because we don't know how these seeds are made and  
17 that's set forth in our contentions.

18           During discovery, and this is also part of our motion  
19 to compel that we were last in front of Your Honor before, one  
20 of the things that we were looking at were for the plaintiffs'  
21 data on some of these prior art samples. Your Honor ordered  
22 that they produce them. The plaintiff still had not produced  
23 them, notwithstanding the January 15th deadline because now  
24 they've made a new assertion of privilege.

25           We took the -- we, then, because we don't have this

1 data from plaintiffs and they refuse to turn it over, we also  
2 evaluated does Example 1 work, because there were holes in  
3 their laboratory notebooks and they didn't have the data.

4 As it turns out, when someone tried to follow their  
5 patent example, it didn't work either. So that was the  
6 evidence that we gathered regarding do these examples work or  
7 not.

8 That's not a new contention. We've always contended  
9 there was not enough detail, including experimental detail in  
10 the specification to let the person of ordinary skill in the  
11 art make any of the hemihydrates that are covered.

12 So all Dr. Cockcroft is doing is taking this evidence  
13 as he's perfectly entitled to do, to show, here's the evidence  
14 of why our contention of non-enablement is correct, and for  
15 the plaintiffs to say, poor us, we might have done something  
16 differently, when we've been asking for that data and those  
17 experiments and those experimental results since the beginning  
18 of this case, Your Honor ordered them to produce it and they  
19 still haven't produced it. To me, it's a really hard pill to  
20 swallow, Your Honor, for them to say that somehow we're doing  
21 something improper here.

22 THE COURT: Well, let me ask you a question here.

23 As I understand plaintiffs' argument, they're saying  
24 the original enablement argument in the contention was that  
25 you can't make all of it. Now the argument is you can't make

1 any of it. Is that right?

2 MS. MAZZOCHI: Well, I don't view them to be as  
3 distinct as the plaintiffs would argue. Our position all  
4 along has been whatever you think your claims cover, you  
5 haven't enabled the full scope. The fact that their own  
6 patent examples don't even work is perfect evidence of why  
7 they haven't enabled the full scope. And even moreover, they  
8 haven't even enabled the one that they promise you in the  
9 specification they were able to make.

10 But that's not a new argument, whether you can or  
11 can't make one or whether you can or can't make any of them,  
12 it doesn't show the enablement argument, which is that the  
13 full scope of your claims can't be made by a person of  
14 ordinary skill in the art without undue experimentation. And  
15 because of the opinions that their other experts in this case  
16 have taken and the positions that they took in their  
17 contentions, that if you don't have a perfectly working  
18 recipe, then the art is too unpredictable for you to ever make  
19 these, even if you're a person of ordinary skill in the art.  
20 That's what the enablement argument was all about.

21 THE COURT: Okay. Question for you.

22 MS. MAZZOCHI: Sure.

23 THE COURT: If the original language or argument in  
24 the contentions says, in my words, you can't make all of it  
25 instead of you can't make any of it, and Dr. Cockcroft

1 testifies to that, does that invalidate the patent?

2 MS. MAZZOCHI: Yes.

3 THE COURT: Okay, I got you. Okay. Anything else?

4 MS. JAMES: Your Honor, this is Ms. James, if I may  
5 reply.

6 THE COURT: Sure.

7 MS. JAMES: Thank you, Your Honor. A lot was just  
8 said and I'm going to try to unpackage it bit by bit.

9 First of all, the accusations about the documents we  
10 were ordered to produce --

11 THE COURT: I'm not -- let me cut you short, because  
12 I don't want to --

13 MS. JAMES: Go ahead, please, Your Honor.

14 THE COURT: That argument that the defendant -- or  
15 the plaintiff didn't produce discovery, in my view, has no  
16 merit. This Court has been available since whenever we  
17 started this case to respond to any discovery dispute. If the  
18 plaintiff had -- the defendant had a problem with discovery,  
19 they should have raised it. Too late to raise it. I'm not  
20 going to entertain any discovery dispute in the context of  
21 this expert's position, so there's no need to address the  
22 argument that their actions are skewed because you didn't  
23 produce discovery.

24 In my view, that argument has no merit and will not  
25 be given any weight. So let's just get to the important

1 issues.

2 MS. JAMES: Yes, Your Honor, thank you.

3 As I understand the local rules, a party needs to  
4 explain in detail what their invalidity contentions are. So,  
5 for example, if the defendants, as Ms. Mazzochi said, they  
6 told us they were going to argue that Example 2 because it  
7 requires the use of a seed was not going to enable one of  
8 ordinary skill in the art to make all of the potential forms  
9 of hemihydrate that could be claimed by Claim 1, that's  
10 different, because they never said in their contentions and I  
11 have not seen a defendant point to a section in their joint  
12 contentions where they say, Example 1, if you follow the  
13 instructions for Example 1, you will not make any form of  
14 canagliflozin hemihydrate. And I do think that although it's  
15 nuanced, they are two totally different arguments to say I  
16 can't -- you can't make all of them, which I think we could  
17 reasonably assume, means they were not going to assert -- you  
18 can't make any, because I know when I read Dr. Cockcroft's  
19 report, I was very surprised to see this argument as well as  
20 the testing that he relies on to say, A, allegedly the example  
21 does not allow one of ordinary skill in the art to make any  
22 canagliflozin hemihydrate.

23 THE COURT: All right. Let me ask you this question.

24 If Dr. Cockcroft has addressed the issue that you  
25 can't make all of it, I take it you wouldn't -- you might

1 object to the substance of it, but you wouldn't object that  
2 it's a late disclosed contention. Is that right?

3 MS. JAMES: Yes, Your Honor, because that would have  
4 been disclosed -- our enablement argument that was disclosed  
5 -- and we want to be reasonable here. If it was disclosed in  
6 the joint contentions, then we would not be making an  
7 application for that, to strike that argument. But that's not  
8 the argument Dr. Cockcroft is making now.

9 THE COURT: Okay. Anything else?

10 MS. JAMES: No, Your Honor. Thank you.

11 THE COURT: Okay. Hold on one moment. Let me just  
12 make a note.

13 Okay. Let's go -- and the last of -- and remember, I  
14 said this was the most straightforward section of the three,  
15 right?

16 MS. JAMES: That's right.

17 THE COURT: Let's go to indefiniteness.

18 Can you tell me what paragraphs are covered by this  
19 argument?

20 MS. JAMES: Your Honor, we're moving to the next  
21 argument on indefiniteness under Section 112, is that correct?

22 THE COURT: What paragraph is covered by that?

23 MS. JAMES: I need to look back at the Cockcroft  
24 report. Excuse me.

25 THE COURT: Because these three arguments, they don't

1 rise or fall together, right? The Court can accept one and  
2 not another, right?

3 MS. JAMES: That is correct, Your Honor. The  
4 indefiniteness section in Dr. Cockcroft's report begins on  
5 Page 47 and ends on Page 52.

6 THE COURT: Okay. Let's hear your argument.

7 MS. JAMES: Your Honor, nowhere in the joint  
8 contentions, and this is a theme that's repeated throughout  
9 our argument and our application, there's nowhere in the joint  
10 contentions that defendants claim that the term -- the word  
11 "hemihydrate" is indefinite. That word "hemihydrate" did  
12 become the subject of claim construction and claim  
13 construction briefing where plaintiffs put forth their  
14 purported construction of that term. That construction was  
15 ultimately adopted by Judge Bumb in her claim construction  
16 order.

17 Throughout the case, the defendants knew what the  
18 plaintiffs were going to argue for the term "hemihydrate" and  
19 what its meaning should be, which was then adopted by the  
20 Court, and nowhere at any time during the course of those  
21 activities in this case the defendants moved to amend their  
22 contentions to add an argument that they believe the term  
23 "hemihydrate" is indefinite.

24 Instead, in their brief, they argue that they're  
25 waiting for the Court's *Markman* opinion and that's why they



1 did not move to amend their contentions. But that should not  
2 excuse their failure to amend their contentions and should not  
3 now provide the basis for Dr. Cockcroft to add a completely  
4 new indefiniteness argument to his expert report.

5 THE COURT: Okay. Let's hear from the defendants.

6 MS. MAZZOCHI: Thank you, Your Honor. The particular  
7 -- if you read the particular paragraphs that the plaintiff is  
8 complaining about in Dr. Cockcroft's expert report, all of the  
9 evidence that's being cited is the '582 Patent, plaintiffs'  
10 *Markman* briefing, and the opinion testimony of their expert  
11 during the *Markman* proceedings, as well as questions by the  
12 Court and plaintiffs' answers during the *Markman* proceedings.

13 So it was always the understanding that plaintiffs --  
14 we didn't think that the plaintiffs should be allowed to get  
15 their construction, and I think that when you look at our  
16 contentions where we talk about indefiniteness, we again say  
17 that to the extent they are suggesting that they should be  
18 able to cover more than one crystalline form, which is what  
19 this approximately argument is all about. On page -- you  
20 know, we start the argument on Page 46, but we again  
21 specifically say the '582 Patent specification does not  
22 explain whether the crystalline form of a canagliflozin  
23 hemihydrate, the prosecution history, does not give any  
24 clarity as to the metes and bounds of the alleged invention,  
25 and again at the very end, we talk about how they obfuscated

1 the scope of the phrase "crystalline form," which is why Claim  
2 1 fails to inform those skilled in the art which crystalline  
3 form of canagliflozin hemihydrate followed in the scope of the  
4 claims of any reasonable certainty. That, that was the whole  
5 point, that there's no reasonable certainty to this  
6 hemihydrate term as the plaintiffs sought to construe it and  
7 argued it during claim construction.

8           They were trying to say that a hemihydrate doesn't  
9 have to have a particular ratio, it can have this approximate  
10 ratio, which it would then allow them to encompass multiple  
11 different crystalline forms, and that's all that Dr. Cockcroft  
12 is noting. And the evidence he's cited is plaintiffs' own  
13 statements from the *Markman* proceedings, for the most part.

14           THE COURT: Are you -- can you tell me what page, if  
15 any, you're referring to in the joint contentions that this  
16 indefinite argument is disclosed?

17           MS. MAZZOCHI: Yes. Pages 46 to 47. And where we  
18 are talking about the indefiniteness issue, because based on  
19 this idea, the plaintiffs' contention that their Claim 1 could  
20 encompass multiple polymorphic forms. The whole dispute with  
21 regard to the term "hemihydrate" -- well, not the only one,  
22 one of the disputes at the *Markman* hearing regarding the claim  
23 term "hemihydrate," is were their claims limited to one  
24 specific form that was disclosed in their specification, or  
25 allegedly disclosed in their specification, or, as plaintiffs

1 argued, did they get an opportunity to cover multiple  
2 crystalline forms, including crystalline forms that had  
3 varying amounts of water.

4 THE COURT: Okay. Can I ask you a question here,  
5 Counsel, because I have Pages 46 to 47 in front of me.

6 MS. MAZZOCHI: Yes.

7 THE COURT: Second sentence says: Specifically, to  
8 the extent plaintiffs contend the phrase, quote, crystalline  
9 form, close quote, covers all blah, blah, blah, blah, and it  
10 goes on to say it is indefinite, okay?

11 MS. MAZZOCHI: Correct.

12 THE COURT: There's no dispute about that disclosure.  
13 Where is a similar disclosure for hemihydrate?

14 MS. MAZZOCHI: Well, because the crystalline form,  
15 that term applies to the hemihydrate. And what would be  
16 argued at the *Markman* hearing is we said that the claims  
17 should be limited to only one particular crystalline form of  
18 the hemihydrate, one that had a certain amount of water, a  
19 certain PGA result, et cetera.

20 The plaintiffs in turn argued that they had a right  
21 to cover a whole range of crystalline forms of the hemihydrate  
22 and they argued that by putting the term "approximate" into  
23 their claim construction was one of the things that allowed  
24 them to cover these multiple crystalline forms.

25 THE COURT: Okay. But you know when we turn the

1 floor over to the plaintiff, you know what they're going to  
2 say. They're going to say, you know, you were clear with  
3 regard to the term "crystalline form."

4 If that was your intent to assert the indefiniteness  
5 argument as to hemihydrate, why weren't you just as clear  
6 instead of going through all these gymnastics?

7 MS. MAZZOCHI: Your Honor -- this is Ms. Mazzochi.  
8 Again, I don't view this as gymnastics. This is the whole  
9 point of being a crystalline form of hemihydrate, and the way  
10 in which the Court construed them, it was a crystalline form  
11 of canagliflozin comprising approximately half a mL of water  
12 to one mL of the compound. That was the construction claim as  
13 argued for.

14 The whole rationale they gave for why they wanted to  
15 get that construction was that they could cover a range of  
16 different crystalline forms. And that's exactly what  
17 Dr. Cockcroft then points out when you are -- when he is  
18 referring to, you know, what is going to be this approximate  
19 range of crystal forms. Is it going to, you know, have this  
20 amount of water or that amount of water, and, you know, if  
21 he's even responding to plaintiffs' invalidity contentions.

22 And then I'm looking for the statement of Dr. Jones.  
23 Dr. Jones -- and this is in Dr. Cockcroft's Paragraph 128. So  
24 their own expert during *Markman* said that this difference in  
25 the water ratio is like -- allows them to cover these

1 different crystalline forms which are going to then manifest  
2 themselves in differences in the analytical techniques and,  
3 you know, this is why he thinks they're going to get these  
4 different environmental conditions and what he referred to as  
5 crystal defects and a whole host of issues.

6           So to me, the plaintiffs in trying to say, oh, let us  
7 divorce crystalline form from hemihydrate, that is completely  
8 the opposite of what they did during the *Markman* proceedings.  
9 Where they were -- where they actually said that that term, "a  
10 crystalline form" allows them the leeway to cover a range of  
11 different hemihydrates.

12           THE COURT: Is it your position, Counsel, that this  
13 particular indefinite argument only accrued after the *Markman*  
14 construction?

15           MS. MAZZOCHI: Yes.

16           THE COURT: So if that's the case, why didn't you  
17 move to amend your contention?

18           MS. MAZZOCHI: Because from our perspective, it's --  
19 I mean, the issue has already been raised and we put in our  
20 contentions, to the extent plaintiffs contend the phrase  
21 "crystalline form" covers crystalline forms of hemihydrate  
22 beyond those disclosed in the specification. That's what they  
23 contended at the *Markman* hearing, and we already said in our  
24 contentions the term is indefinite.

25           THE COURT: Okay. Anything else? Okay. Let's hear

1 from plaintiffs' reply and then we will move on.

2 MS. JAMES: Thank you, Your Honor. Again, for the  
3 record, this is Colleen James. Again, we -- you know, we've  
4 heard defendants' counsel cite to the *Markman* transcript from  
5 the hearing, citing to a deposition transcript from  
6 plaintiffs' expert in support of their *Markman* positions, but  
7 we have yet to find where in the joint contentions  
8 Dr. Cockcroft's indefinite arguments are.

9 And Dr. Cockcroft makes specific indefinites  
10 arguments when it comes to hemihydrate. He's taking issue  
11 with plaintiffs' proposed construction and the construction  
12 the Court adopted that includes the term "approximately."  
13 Approximately half a mL of water to one mL of compound and  
14 Dr. Cockcroft is taking issue with the term "approximately" as  
15 it's used to define hemihydrate. That idea, that concept is  
16 nowhere in the joint contentions.

17 Again, Dr. Cockcroft is taking issue with the term  
18 "substantially" in Claim 3 and 4 of the patent, as indefinite.  
19 Again, when I look at the joint contentions, I don't see any  
20 discussion of the term "substantially" in Claims 3 and 4 of  
21 the '582 Patent as being indefinite.

22 We know under the local rules, a *Markman* order or  
23 decision is potentially grounds to amend their contentions,  
24 and thought that if plaintiffs -- excuse me -- the defendants  
25 were going to have these invalidity indefinites arguments,

1 they would amend their contentions as they are required to do  
2 to include these arguments. That time came and went and they  
3 didn't, and to our surprise, we now see these arguments in  
4 Dr. Cockcroft's report, which we believe is a violation of the  
5 local patent rules.

6 THE COURT: Okay.

7 MS. MAZZOCHI: Your Honor, this is Ms. Mazzochi.  
8 Because the plaintiffs just raised the "substantially" issue.  
9 We have explicitly, Page 58 of the contentions, defendants  
10 also assert that Claim 3 of the '582 Patent is invalid because  
11 the phrase "substantially the same" is indefinite.

12 So we clearly also put that as well into our  
13 contentions. So I don't -- you know, that got slid in there  
14 and I don't think there's been any dispute that we didn't  
15 disclose that particular issue.

16 I think that where we seem to have an impact with  
17 plaintiff is that the plaintiff seems to think we should have  
18 put all of our evidence into our contentions and the fact that  
19 we developed evidence to support our contentions later on,  
20 which Dr. Cockcroft is now relying on, I don't view that as a  
21 new theory. We have new evidence, we don't necessarily have a  
22 new theory.

23 What Dr. Cockcroft is pointing out is that the  
24 plaintiffs "approximately" word, term, from the claim  
25 construction as applied to hemihydrate is what is allowing the

1 claims to cover multiple hydrate forms, which is exactly what  
2 we complained about in our original contentions.

3 And I don't read the New Jersey local patent rules as  
4 saying we have a duty for our contentions, certainly not on  
5 112, to recite every piece of evidence that we plan to rely  
6 on. And if that's the pathway we're going to go down, then we  
7 will be back in front of Your Honor, because the bulk of the  
8 evidence that the plaintiffs are relying on, likewise, was not  
9 disclosed in many of their contentions. Maybe their theory  
10 was, but not the evidence.

11 And I think that's the problem here, is that the  
12 plaintiffs are suggesting that because we -- Dr. Cockcroft is  
13 reciting evidence of the theory, that that means they went on  
14 notice of the theory, and I just -- I can't agree to that.

15 THE COURT: Okay. Let's move on to anticipation.  
16 Plaintiff?

17 MS. JAMES: Thank you, Your Honor -- sorry.

18 THE COURT: Are we going to divide this up like we  
19 did with Section 112?

20 MS. JAMES: No. This is just one -- this argument  
21 doesn't have subparts.

22 THE COURT: Good.

23 (Laughter.)

24 MS. JAMES: Yes, hopefully, this will go a little  
25 faster, Your Honor, and I will do my best to make that happen.



1           We're now turning to Dr. Eckhardt's expert report,  
2 and in Dr. Eckhardt's report, he describes an argument that's  
3 titled an anticipation argument, and it appears to us that  
4 he's arguing that the patent is allegedly invalid under an  
5 anticipation theory based on a document referred to as the WO  
6 '326 Patent Application, in light of other references that  
7 talk about hydrates and Janssen internal documents.

8           In the joint contentions, there is no discussion of  
9 an anticipation argument that relies on hydrate references and  
10 Janssen internal documents.

11           The joint contentions do disclose an argument based  
12 on WO '326 itself, but there's no other discussion about the  
13 hydrate references in the Janssen internal document, and these  
14 are documents that should have been identified in the joint  
15 contentions if they are going to be the basis for any  
16 invalidity argument.

17           The local rules require defendants to specifically  
18 identify all individual references that they claim anticipate  
19 the patents, even though the defendants admit the Janssen  
20 internal document are not technically classic prior art. For  
21 the purposes of disclosure under the local patent rules,  
22 documents like the Janssen documents that they're relying on  
23 for their invalidity theory would need to be disclosed, and  
24 they did not do that.

25           They seemed to again intimate in their letter that

1 these Janssen documents were amongst the documents that  
2 plaintiffs produced late in December 2019. The Janssen  
3 documents that Dr. Eckhardt is now relying on were produced in  
4 2018. So there does not seem to us any reason why the  
5 defendants could not have been -- were not aware of them at  
6 that time and could not have cited them in their contentions  
7 at that time.

8 Because they failed to do so, and amend their  
9 contentions throughout this entire litigation, we do not  
10 believe that Dr. Eckhardt should now be entitled to rewrite  
11 the contentions and base an anticipation argument on these  
12 hydrate references and Janssen internal documents.

13 THE COURT: Okay. Let's go to defendant.

14 MS. MAZZOCHI: Thank you, Your Honor, again, this is  
15 Ms. Mazzochi. I think that a case that would be instructive  
16 for Your Honor on this issue is *Monsanto Tech, LLC versus E.I.*  
17 *DuPont de Nemours and Company*, 878, F.3d, 1336 at Page 1345,  
18 Federal Circuit 2018.

19 And in that case, there was a dispute between the two  
20 parties as to whether certain evidence, such as a declaration  
21 and other things that were called extrinsic evidence, whether  
22 that was prior art when you're talking about an anticipation  
23 defense, and what the Federal Circuit said -- and I think that  
24 the plaintiffs here are in the same position as *Monsanto*  
25 there. The Federal Circuit said, however, *Monsanto* confuses

1 prior art with extrinsic evidence used to support what is,  
2 quote, necessarily present, close quote, in a prior art's  
3 teaching.

4           So here again, there's no dispute that in our  
5 contentions, at Pages 24 to 25, we argued that the '326 Patent  
6 discloses a hydrated polymorphic form of canagliflozin and we  
7 specifically said, this is on Page 25, the Vero '326 also  
8 inherently describes every limitation of Claim 1 of the '582  
9 Patent.

10           So similarly, what we are using these other  
11 references for and what we are using the Janssen documents  
12 for, is to show what was inherently within the WO '326  
13 reference. They're not, themselves, stand-alone independent  
14 prior art.

15           So, for example, in our -- on Page 25, we say WO '326  
16 teaches that well-known and conventional methods may be used  
17 for the isolation and purification of canagliflozin. These  
18 well-known methods in the art include recrystallization and  
19 they gave the citations to that.

20           Now, the plaintiffs in their contentions have come  
21 back to say, well, we don't think that's enough to, for  
22 example, give you a recipe of that -- you know, the person of  
23 ordinary skill in the art couldn't use that to make  
24 hemihydrate. What Dr. Eckhardt has done is identified  
25 evidence, not a new theory, it's evidence showing that these

1 existed teachings in the '326 Patent, you know, allowed the  
2 hemihydrate or enabled the form of the hemihydrate to be  
3 necessarily present in this prior art teaching.

4           So this again is, I think, where we're getting into  
5 this distinction between the local rules don't require us to  
6 submit every piece of evidence, we have to identify the  
7 contention. And these particular pieces of evidence that  
8 Dr. Eckhardt is relying on, including that Janssen itself was  
9 able to make some hemihydrate without any difficulty following  
10 synthetic steps set forth in the '326 Patent, you know, shows  
11 that this was an inherent disclosure within the '326 Patent,  
12 and I think that the *Monsanto* case kind of gives the framework  
13 for how to think about it.

14           Another one that the *Monsanto* case cites, *In Re*  
15 *Baxter Travenol Labs*, 952 F.2d 388 at 390, Fed Circuit 1991.  
16 In that case, there was a question about whether a particular  
17 plastic in this prior art material has certain leachable  
18 qualities.

19           The patent challengers were allowed to go outside the  
20 reference to say, this is what we know is inside the reference  
21 and that was okay. It's not prior art when you go outside the  
22 reference.

23           So we're not trying to say that the Janssen documents  
24 that are being relied on for this purpose are themselves an  
25 independent prior art citation. We're just saying that it's

1 evidence that confirms our contention about inherency is  
2 correct, and the plaintiffs' contention about inherency is  
3 wrong.

4 THE COURT: Got it. Thank you.

5 Plaintiff, last word.

6 MS. JAMES: Thank you, Your Honor. This is Colleen  
7 James. We can debate at another time the law of inherent  
8 anticipation and the fact that technically under the law, you  
9 only can rely on a single document to prove anticipation, and  
10 here, as I heard Ms. Mazzochi say, she called the Janssen  
11 documents extrinsic evidence and I believe and understand that  
12 the local rules, whether you call it prior art or extrinsic  
13 evidence or something else, however you want to label it, if  
14 it's something you believe is evidence to your argument and  
15 you are aware of it, because we produced it to you in this  
16 case, you need to cite it in your invalidity contentions if  
17 you would like to rely on it during expert discovery.

18 Defendants did not do that and they had every  
19 opportunity to do that throughout this litigation and now  
20 should not be able to sneak in all of these references that  
21 were known in 2008 during expert discovery -- 2018.

22 THE COURT: Okay. Thank you. All right. Last is  
23 the obviousness issue and as I understand the argument from  
24 reading the papers, there's four subsections to this. Is that  
25 right, Plaintiff?

1 MS. JAMES: I put them in three buckets, Your Honor,  
2 which maybe makes it a little easier to have one less bucket  
3 for Your Honor to deal with today.

4 THE COURT: Well, the less the better, that's for  
5 sure. I mean, the new combination, the new references, and  
6 the new theories. Is that the three buckets?

7 MS. JAMES: I have bucket 1 -- if you'll indulge me  
8 for a minute, Your Honor, so make sure we all get on the same  
9 page to have the right framework going forward.

10 Bucket 1, I grouped together, never disclose  
11 references and combinations.

12 THE COURT: Right.

13 MS. JAMES: Bucket 2 is previously disclosed  
14 references, but they're being cited for a different purpose.

15 And bucket 3, the addition of a knowledge to a POSA  
16 to the combinations.

17 THE COURT: Okay.

18 MS. JAMES: I'm happy to do it any way Your Honor  
19 prefers.

20 THE COURT: It's your application, so we'll do it  
21 your way.

22 So, let's start -- let's do obviousness. We know,  
23 generally, we're talking about Paragraphs 299 to 365 of  
24 Eckhardt.

25 Your first bucket is what?

1 MS. JAMES: The first bucket is references that were  
2 never disclosed in the joint contentions and combinations that  
3 were never disclosed in the joint contentions.

4 THE COURT: And can you -- excuse me. Are you able  
5 to identify the paragraph of Eckhardt report saying if the  
6 Court agreed with you that what paragraphs would be stricken?

7 MS. JAMES: Yes, Your Honor, that is -- we endeavored  
8 to do that in our exhibits to try to be fair and went through  
9 the report to highlight the sections that should be stricken,  
10 which in some cases isn't the entire paragraph on a page.

11 THE COURT: It's just the highlighted portion?

12 MS. JAMES: That's correct, Your Honor.

13 THE COURT: Okay. Can I go back a step? There was a  
14 question I meant to ask you earlier on, that I neglected to  
15 ask.

16 Have all of plaintiffs' expert reports been produced?

17 MS. JAMES: Yes, we have responded to the defendants'  
18 reports.

19 THE COURT: And have expert depositions been taken?

20 MS. JAMES: No, Your Honor, the parties are still in  
21 the expert -- the expert report phase. The parties have yet  
22 to exchange reply expert reports.

23 THE COURT: All right. In plaintiffs' expert  
24 reports, either the reports that were already served or to be  
25 served, do they address the issues that you're seeking to

1 strike?

2 MS. JAMES: Unfortunately, Your Honor, given the  
3 timing of defendants' invalidity expert reports and the fact  
4 that we only had four weeks to respond and did not renew --  
5 our application might not be decided by Your Honor before  
6 then, we did take the safer approach and we did respond to all  
7 of the defendants' invalidity expert opinions, even though we  
8 believe that many of them are inappropriate.

9 THE COURT: So again, hypothetical, I'm not ruling.  
10 If the Court struck or granted all or part of plaintiffs'  
11 application, would plaintiff remove those portions of the  
12 expert submissions that respond to the portions of defendants'  
13 reports that are stricken?

14 MS. JAMES: Your Honor, yes, we could certainly do  
15 that if that is the Court's preference.

16 THE COURT: Well, you tell -- I mean, why would you  
17 want to keep it in?

18 MS. JAMES: We wouldn't need to, Your Honor.

19 THE COURT: Okay.

20 MS. JAMES: We only put it in in the first place to  
21 respond within the time frame that we were allotted. But if  
22 Your Honor were to rule our way, we agree that those issues  
23 can be removed from the case and the case can be streamlined  
24 going forward.

25 THE COURT: All right. Let's go to obviousness.



1 Reference to Category 1 -- Subcategory 1: References not  
2 Disclosed in the Joint Contentions and the Combinations Not  
3 Disclosed in the Joint Contentions.

4 MS. JAMES: Okay. So the local rule is very clear on  
5 this, that the defendants need to not only identify each item  
6 of prior art that allegedly renders each asserted claim  
7 obvious, but they also have to explain why that prior art  
8 renders the asserted claim obvious by pointing to specific  
9 sections in the references, and the local rules are pretty  
10 explicit on this.

11 Defendants' expert, Dr. Eckhardt, cites approximately  
12 56 new references that were never identified in the joint  
13 contentions. The fact that many of these newly cited  
14 references are Janssen internal documents does not, in our  
15 view, excuse defendants from the requirement that they must be  
16 disclosed.

17 Plaintiffs produced over a million pages of documents  
18 in this litigation, and in their response to our application,  
19 defendants try to shift the burden to us by suggesting that we  
20 should be aware of the internal documents in our document  
21 production that defendants are planning or were planning to  
22 rely on in their expert reports.

23 That's not our job. The defendants' job is to  
24 identify the documents in our production they were planning on  
25 relying on, and it would have been helpful for us to know that

1 they were going to make these arguments and rely on these  
2 documents well early in the litigation, as they were required  
3 to do. I think that it would have, you know, shaped our  
4 strategy, our questioning at depositions, and we were deprived  
5 of a lot of those opportunities because the defendants did not  
6 disclose these documents until February of this year.

7 Defendants don't dispute that -- they don't dispute  
8 this, that the references were not disclosed. They don't  
9 dispute the Janssen documents were not disclosed, and the  
10 other references that were not disclosed in this group, they  
11 -- the defendants' claim are just background information or  
12 references to confirm the state of art.

13 THE COURT: Hold on one second, Counsel. Did someone  
14 just call in for the 3:30 call?

15 MR. STINSON: Yes, this is John Stinson from the  
16 government, Your Honor.

17 THE COURT: Okay. Can I ask your indulgence,  
18 Counsel? We're going a little bit longer on the 2 o'clock  
19 call that I thought we would. Could you call in at 4?

20 MR. STINSON: I'm happy to call in at 4, Your Honor.  
21 If Mr. Molz is not hearing this right now, I'll shoot his  
22 office an e-mail.

23 MR. MOLZ: I'm here.

24 THE COURT: Can you call in at 4, Mr. Molz? We're  
25 going a little bit longer.

1 MR. MOLZ: Sure, absolutely. Thank you, Your Honor.  
2 Bye-bye.

3 THE COURT: Counsel, just so you know, this is a  
4 great conference call system that they set us up with. The  
5 only problem is, there's no firewall between the calls, so if  
6 you go a little bit longer on a call than anticipated, the  
7 next call comes right into your call. So those two people who  
8 called in have nothing to do with this case and that's why I  
9 excused them.

10 MS. JAMES: We understand. Thank you, Your Honor.

11 THE COURT: Let's continue.

12 MS. JAMES: Thank you, Your Honor. As I was saying,  
13 the defendants do not dispute that the Janssen documents were  
14 not disclosed in the invalidity contentions and they also  
15 cannot dispute that other references were not disclosed in the  
16 joint contentions. Like, for example, the Etter reference was  
17 not disclosed in the joint contentions, and the Etter  
18 reference is now a reference that has appeared in defendants'  
19 combinations of obviousness. So not only did they also did  
20 not disclose a reference, they also did not disclose a  
21 combination using that reference, and in their opposition,  
22 they said that we should have figured out that they were going  
23 to use the Etter reference in a combination because the Etter  
24 reference was cited in the Deseraju reference.

25 And again, you know, the position that the defendants

1 have repeatedly put us in in this case with respect to this  
2 contention and the extra reports is that we would have to go  
3 look through every reference and every citation in every  
4 reference to piece together and figure out what their  
5 combinations were going to be. And the local rule  
6 specifically make it clear that plaintiff should not have to  
7 go through this detective work to try to figure out what  
8 combinations are being asserted for obviousness.

9           The similar -- with the Jeffrey article was not cited  
10 in the joint contentions and defendants now try to excuse this  
11 fact by arguing that Jeffrey discloses similar concepts as  
12 other references that were explicitly cited. Again, without  
13 specifically disclosing the Jeffrey or the Etter references,  
14 defendant should not now be allowed to, A, rely on them, and  
15 B, add them as part of -- as part of obviousness combinations  
16 when those were not disclosed in the contentions.

17           And if it would help, Your Honor, in our reply  
18 opposition brief starting on Page 6, we put together a chart,  
19 and if Your Honor has that, it might be easier for me to walk  
20 the Court through the chart.

21           THE COURT: Let me pull it up. Hold on one moment.

22           MS. JAMES: Yes, Your Honor.

23           THE COURT: That's the most recent brief, right?

24           MS. JAMES: That's correct, on March 24th.

25           THE COURT: I'm working from my iPad, so just bear

1 with me.

2 MS. JAMES: Of course, Your Honor.

3 THE COURT: Okay. While it's loading, you know -- I  
4 don't have it in front me, it's loading right now, but you can  
5 continue with your argument.

6 MS. JAMES: Okay. You'll see, Your Honor, when you  
7 pull up the letter brief on Page 6, there's a chart, and the  
8 chart shows nine combinations that now appear in the Eckhardt  
9 report.

10 The defendants' joint contentions disclose only four  
11 combinations and those are the combinations that plaintiffs  
12 have been moving forward and relying on during this entire  
13 case.

14 Now -- and we've set it forth in table -- in the  
15 table on Page 6, the defendants are adding references to  
16 combinations, such as -- would you like me to pause, Your  
17 Honor?

18 THE COURT: No, go ahead.

19 MS. JAMES: Okay. Such as, for example, in New  
20 Combination 4, defendants add Hilfiker. Hilfiker was  
21 described in the joint contentions in a footnote and Hilfiker,  
22 just to give the Court some perspective, is a 600-page  
23 scientific book that actually is comprised of many different  
24 sections written by different scientists and the defendant  
25 cited two pages.

1           Now, in Dr. Eckhardt's expert report, Hilfiker is  
2 part of a combination, not just in a footnote in the joint  
3 contentions citing to two pages, it's a 600-page book that the  
4 defendants are now using in one of their combinations and  
5 they're citing to all other parts of Hilfiker.

6           There is no way that we could have anticipated that  
7 they would have used Hilfiker in a combination when they  
8 talked about in their joint contentions but didn't put it as  
9 part of their contention, and nor were we able to foresee that  
10 they would rely on other parts of this very voluminous  
11 600-page-plus textbook for other arguments.

12           Again, then they add five brand new combinations that  
13 were never disclosed in the joint contentions and those are  
14 Combinations 5, 6, 7, and 9 -- excuse me, four combinations,  
15 6, 7, and 9 that are brand new combinations never disclosed in  
16 the joint contentions.

17           THE COURT: What about -- I'm sorry, I'm looking at  
18 it now, 5, 6, 7, 8, 9 says "combination not listed."

19           MS. JAMES: Yes. Those combinations, 5, 6, 7, and 9  
20 were never disclosed in the joint contentions. Those are  
21 brand new --

22           THE COURT: What about 7 and 8?

23           MS. JAMES: So, 5, 6, 7, and 9 were never disclosed.  
24 8 was disclosed, but in the Sandoz contentions.

25           THE COURT: Oh, okay.

1 MS. JAMES: Okay? And that's another problem here,  
2 Your Honor, is one of the things the defendants have kind of  
3 forced us to do is not only look and try to figure out from  
4 the joint contentions what combinations and what prior art  
5 they're relying on.

6 THE COURT: Why am I worried about the Sandoz  
7 contentions? Aren't we just talking about these defendants?  
8 I mean, I'm assuming, correct me if I'm wrong, that even if it  
9 was disclosed in the Sandoz contentions, if it's not in these  
10 defendants' contentions, you're seeking to strike it. Am I  
11 wrong?

12 MS. JAMES: No, you're correct, Your Honor.

13 THE COURT: So why do I give a hoot whether it was  
14 disclosed to Sandoz or not?

15 MS. JAMES: We agree with Your Honor.

16 MR. REMUS: Your Honor, this is Mark Remus on behalf  
17 of Sandoz. May I be heard?

18 THE COURT: If it's relevant to this point.

19 MR. REMUS: It absolutely is. Sandoz is a party to  
20 the Cockcroft and Eckhardt reports. So, to the extent the  
21 Court strikes any portions from those reports, it would be  
22 prejudicial to Sandoz because Sandoz has disclosed these  
23 contentions in its own contentions. So that's why the Sandoz  
24 contentions are relevant.

25 THE COURT: Okay. Hold on one second because -- bear

1 with me. All I'm concerned about is these portions of the  
2 expert -- of these two expert reports that were submitted  
3 by -- somewhere I have a list of who submitted these expert  
4 reports.

5 I'm not -- plaintiff hasn't moved to strike anything  
6 of Sandoz.

7 MR. REMUS: It has, though. No, it has. Because the  
8 Eckhardt and Cockcroft reports were submitted on behalf of  
9 Sandoz in addition to all of the other defendants.

10 THE COURT: All right. I don't think we -- I don't  
11 think we have a disagreement. Let me just see if I can state  
12 it right.

13 Somewhere in these notes of mine, I have a list of  
14 the defendants who submitted these joint contentions. I take  
15 it -- and the joint contentions we're talking about are  
16 Exhibit 1, dated March 30th, 2018, correct?

17 MR. REMUS: Correct.

18 THE COURT: Okay. So ultimately, the Court has to  
19 rule as to whether those defendants who submitted this joint  
20 contention on March 30th, 2018, can rely on the portions of  
21 these two expert reports that we're dealing with. That  
22 doesn't involve Sandoz.

23 MR. REMUS: It does, Your Honor, because --

24 THE COURT: No, it doesn't. Because the Court can  
25 bar four or five defendants from relying on the paragraph, but



1 that doesn't mean Sandoz can't rely on it, right?

2 MR. REMUS: If that's what Your Honor rules, yes.

3 THE COURT: Okay.

4 MR. REMUS: Our concern is to the extent they are  
5 stricken entirely, we would certainly object to that.

6 THE COURT: I gotcha. But the Court -- the only  
7 issue before the Court is whether these -- the defendants who  
8 submitted the joint contentions on March 30, 2018, can rely on  
9 those portions of the two expert reports. That does not  
10 involve Sandoz. So we're -- okay, we're on the same page.

11 MR. REMUS: I think we are. But just to clarify,  
12 Sandoz signed on to both the joint contentions as well as its  
13 separate invalidity contentions. So I just want to make sure  
14 Your Honor appreciated that.

15 THE COURT: To the extent it relied on the March 30,  
16 '18 contentions, it rises or falls with the Court's ruling.  
17 I'm not addressing Sandoz's separate March 30th, 2018  
18 contentions, okay?

19 MR. REMUS: I understand, Your Honor. Thank you.

20 THE COURT: Plaintiff, let's move on.

21 MS. JAMES: Thank you, Your Honor. Just to note on  
22 this point, Dr. Eckhardt, in his materials considered, listed  
23 the joint contentions, but he did not list the Sandoz  
24 contentions. So in our view, Dr. Eckhardt did not consider  
25 those contentions when rendering his expert opinion.

1           THE COURT: That sounds like an evidentiary issue for  
2 trial.

3           MS. JAMES: Thank you, Your Honor.

4           THE COURT: I suspect you're going to file a motion  
5 in limine on that.

6           MS. JAMES: Your Honor, I'm happy to answer more  
7 questions. I think our chart on Page 6 in our reply report  
8 sets forth this issue pretty clearly. I'm happy to answer any  
9 of the Court's questions, but also happy to move on to the  
10 next issue.

11           THE COURT: I got it. We have to wrap up by  
12 4 o'clock, so let's see if we can move this along.

13           MS. JAMES: Yes, Your Honor. Would you like to hear  
14 from the defendants or would you like me to move on to the  
15 next bucket?

16           THE COURT: No, no. Let's hear from the defendants  
17 on the first, what you call a bucket -- references not  
18 disclosed in joint contentions and combinations not disclosed.

19           Defendant?

20           MS. MAZZOCHI: Yes. Thank you, Your Honor. Again,  
21 this is Ms. Mazzochi. I think that we're -- we have a bit of  
22 a disconnect between our understanding and plaintiffs' in  
23 terms of how plaintiffs are interpreting the expert report, is  
24 that -- of Dr. Eckhardt. You know, when Dr. Eckhardt is  
25 talking about various, you know, the materials he combined

1 together to reach a conclusion, he's pointing to everything --  
2 not everything, but he's pointing to the salient points that  
3 he relied on a reference for, and a lot of these references  
4 are all kind of saying the same thing, you know, in different  
5 ways.

6 But when you look at what the plaintiffs are really  
7 objecting to, in the paragraph that they're pointing to, he's  
8 not doing more combinations, more references. Again, you  
9 know, and we put in our brief where we think that the  
10 plaintiffs are wrong, that these, in fact, were included in  
11 our contentions and they were put in our claim charts,  
12 including combination. So we just -- we don't understand  
13 where the plaintiffs are coming from, because when you look at  
14 our contentions directly and our claim charts, a lot of these,  
15 you know, these things that they're saying were not disclosed  
16 were actually disclosed, including in combination.

17 The only exception I think to that one, would be  
18 Combination No. 9 to the extent it references Jeffrey and  
19 Etter because we did -- none of the defendants knew about  
20 Jeffrey or Etter. They referenced -- those are two references  
21 that Dr. Eckhardt himself identified while he was preparing  
22 his report, and to be perfectly honest, Your Honor, what he's  
23 citing them for is to talk about a principle of hydrogen  
24 bonding. It's not -- they're not being disclosed to say, here  
25 is the elements of hemihydrate, or here is the elements of

1 canagliflozin.

2           So here again, this is why we get to the point where  
3 we think the plaintiffs are grossly misreading the local rules  
4 and what's required in the invalidity contentions.

5           So in our invalidity contentions, we have offered the  
6 theory, here is where canagliflozin is disclosed, here are the  
7 various references that we think teach you how to make a  
8 crystalline hydrate or how to make a crystalline polymorph  
9 that in turn would be a hemihydrate.

10           Those are disclosed and they don't dispute that those  
11 are disclosed. What they're objecting to, and we can see this  
12 when you start reading some of the sections that they've  
13 highlighted from Dr. Eckhardt, what they're objecting to is  
14 Dr. Eckhardt addressing the substance of their validity  
15 contentions.

16           So, for example, if you look at Dr. Eckhardt's  
17 Paragraph 308, he says plaintiffs argue one would have pursued  
18 a chromatography method of purification and he cites to the  
19 plaintiffs' contentions, but then he says, but this was done  
20 using organics material which is one of the things that  
21 plaintiffs are saying is a new reference. It's not a new  
22 reference, it's evidence. It's their own documentary evidence  
23 that contradicts their own contentions.

24           Now, they're saying they want Dr. Eckhardt to  
25 withdraw in his opening report his response to their

1 contentions and then only offer his response to their  
2 contentions in his reply report.

3 I guess we could do that, but he was trying to  
4 address all of the issues that had been raised in his opening  
5 report so that the plaintiffs to then respond which -- and  
6 they've admitted, they've done, is they want to then say, oh,  
7 no, we're now withdrawing our contention on this issue, and I  
8 don't need Dr. Eckhardt to opine on it, and use this document  
9 to prove that the plaintiffs were wrong, but the whole point  
10 is they're not withdrawing their contention.

11 So that's why in response to their contention, he  
12 said, this is why it's wrong.

13 Likewise, Paragraph 309, same -- you know, same  
14 thing, he's responding to the plaintiffs' contention, when it  
15 comes to the Hilfiker reference that the plaintiffs complained  
16 about, that's in Paragraph 313, he -- all he's saying is,  
17 well, it's referencing the same concept.

18 Well, that's not a new contention, it's not a new  
19 reference, it's not a new theory, it's just pointing -- and  
20 the Hilfiker reference was disclosed, it's not a new  
21 combination, per se. It's simply pointing out these same sets  
22 of teachings which we've already identified in the contentions  
23 appear in multiple references.

24 So, you know, for the plaintiff to say that we should  
25 have somehow preassembled all of our evidence into the local

1 rule patent contentions, the local rule contentions are not  
2 the final pretrial order. They're not supposed to be expert  
3 reports, and this is why we asked the plaintiffs to identify,  
4 tell us where there's a local patent location, New Jersey,  
5 that says, we are -- we have a duty to disclose every piece of  
6 evidence, particularly every piece of evidence that we want to  
7 -- including our own internal documents that we could use to  
8 rebut your own contention. That's not what the rule is.

9           When you look at what the rule is, did we identify  
10 the prior art references we're relying on? Yes. Part B, did  
11 we explain why in the contentions we think these references  
12 are relevant? Yes, because they are, they talk about certain  
13 ways to make polymorphs and they talk about why you screen  
14 polymorphs or whatever.

15           Then a chart identifying what in the prior art  
16 references we're planning on using. We did that, and that's  
17 why we were able to cite for Your Honor in our responsive  
18 letter on Pages 6 to 7, where, in our charts and in our  
19 contentions, we disclosed all of these combinations -- I'm  
20 sorry, that's on Pages 5 to 6. 6 to 7 was their new theory  
21 but we also show where we had those as well.

22           So when it comes to the --

23           THE COURT: Hold on, Counsel, we have to move this  
24 along. We have got ten minutes.

25           MS. MAZZOCHI: Sure.

1 THE COURT: We've been at this almost two hours.

2 Let's move this along, all right?

3 MS. MAZZOCHI: That's fine, Your Honor.

4 THE COURT: I heard enough on this point.

5 Plaintiff, what's the second bucket, real quick.

6 MS. JAMES: Real quick, second bucket: Previously  
7 Disclosed Prior Art For a New Purpose. The local rules  
8 specifically call for not just an identification of the  
9 reference, but also the specific section of the reference on  
10 which defendants intend to rely.

11 In the joint contentions, defendants cited several  
12 sections of certain references for their obviousness  
13 arguments. However, Dr. Eckhardt in his report cited to  
14 entirely new sections of those references for support for his  
15 opinions. This is improper.

16 THE COURT: Defendant?

17 MS. MAZZOCHI: We disagree that, A, we've done what  
18 the plaintiff accused us of doing, and B, as we understand the  
19 local rules, an expert is not precluded from responding to the  
20 plaintiffs' contentions by looking at other points of the  
21 reference that contradict the plaintiffs' contentions about  
22 that reference.

23 So here again, we have our contentions as to what we  
24 think the evidence shows. They want to come back and say, no,  
25 we don't think it shows that, and then we respond, yes, it

1 does. If they want to withdraw their contentions, we can  
2 probably withdraw some of these. But since we know they're  
3 going to make them, Dr. Eckhardt shouldn't be precluded on the  
4 scope of what he's allowed to rely on in rebuttal and --

5 THE COURT: Okay, I got it.

6 Plaintiff, third point, third bucket.

7 MS. JAMES: Third bucket: Addition of Knowledge of  
8 POSA to a Combination.

9 The language or the knowledge of a POSA as a catchall  
10 was not in many of the combinations in the joint contentions,  
11 but now Dr. Eckhardt is tacking that language on to his  
12 combinations and it does not provide the disclosure of  
13 specific references and specific sections of each reference  
14 that allegedly renders the claims obvious.

15 So, in fact, you know, knowledge of a POSA language  
16 to obviousness combination to choose the exact opposite  
17 result, it leaves open the option for defendant to backdoor  
18 any reference in, that -- that's within the knowledge of a  
19 POSA, and that can be an infinite number of references.

20 As we pointed out in our chart, every time that the  
21 defendants put knowledge of a POSA -- have added knowledge to  
22 a POSA to their combinations, we think that is improper,  
23 because in their contentions, they have to list out the  
24 specific references and can't just say "knowledge of a POSA"  
25 and leave the plaintiffs to try to figure out and decide



1 amongst the infinite number of references within the knowledge  
2 of a POSA what the defendants could possibly be talking about  
3 that they would be relying on in their expert reports, and  
4 that's what happened and they ended up surprising and  
5 sandbagging us with other references that were never disclosed  
6 in Dr. Eckhardt's expert report. Thank you, Your Honor.

7 THE COURT: Defendant?

8 MS. MAZZOCHI: Yes. No. 1, the plaintiffs can't say,  
9 ignore the knowledge and scope of a person of ordinary skill  
10 in the art. That is part of the obviousness test. The  
11 Supreme Court has also said in the KSR decision that you can  
12 rely on the knowledge and scope of a person of ordinary skill  
13 in the art in an obviousness combination, because they  
14 recognized not everything a person of ordinary skill in the  
15 art knows is set forth in a little article or in a piece of  
16 paper that was published.

17 To the extent we have a publication or a prior art  
18 reference that we are relying on, again with the two that I  
19 identified, Jeffrey and Etter, which Dr. Eckhardt  
20 independently identified while he was preparing his reports,  
21 all of the prior art references we have identified and plan to  
22 rely on are in there.

23 To the extent that plaintiffs are raising some  
24 issues, for example, like there's a Berenstein 2002 reference  
25 that they complain Dr. Cockcroft is citing. Well, they cited

1 that same reference in their own validity contentions.

2 So they get to somehow talk about it and we don't get  
3 to respond? That can't be right. One of the references  
4 they're complaining about, Stahly 2007. We're not relying on  
5 that as prior art, we're relying on it to just show some --  
6 you know, that one of the allegations that the plaintiffs had  
7 made in their own contentions about the state of the art were  
8 wrong.

9 So for the plaintiffs to start saying that, you know,  
10 that we can't somehow talk about the knowledge and skill sets  
11 of a person of ordinary skill in the art would mean to set  
12 this trial up for failure because the expert has to be able to  
13 talk about that. They may disagree with it and that's the  
14 topic of cross-examination, but it's not something that we  
15 were required to disclose in the -- under the local rules and  
16 didn't. If it's involved in the prior art, we've got it  
17 disclosed.

18 THE COURT: Okay. Thank you.

19 All right. Counsel, I think the record is extensive.  
20 Your written submissions were terrific, oral argument, the  
21 same. The Court is reserving decision. I want to get the  
22 transcript of this argument.

23 I'm going to do one of two things. I'm either going  
24 to reconvene this call to just fine-tune a couple of  
25 questions, or just read an oral opinion into the record to be

1 confirmed with an order.

2           Either way, the next call we have, the Court's going  
3 to rule. It's just a matter if we may have a second session  
4 of oral argument, and I don't know right now. I'm aware of  
5 the trial date, I know the issue should be addressed promptly,  
6 and will. I thank you for your extensive effort.

7           For the good of the order, are there any other issues  
8 or matters we need to address before we adjourn?

9           MS. JAMES: This is Colleen James. No, for  
10 plaintiffs, Your Honor. Thank you very much for your time.

11           MS. MAZZOCHI: On behalf of the defendants, Your  
12 Honor, we certainly will try and go through the transcript as  
13 well and if there's lack of clarity, we apologize in advance  
14 and we will certainly try to address that.

15           In view of some of the assertions that were made by  
16 the plaintiffs today, you may see an additional round of  
17 motions to strike from us based on what some of the standards  
18 are going to be that they propose.

19           MR. BATON: Your Honor, this is Bill Baton. There is  
20 an issue. You know, I know Your Honor -- we're trying to  
21 observe Your Honor's directive that all, you know, deadlines  
22 remain in place. I don't know if you're aware, but there were  
23 some discussions in the related case, the compound case before  
24 Chief Judge Wolfson and Judge Arpert. There was a final  
25 pretrial conference and that case was supposed to go to trial

1 in May and that is very much up in the air at this time.

2 I believe Mr. Sterns was on the phone -- just been in  
3 that conference, and there are some complications with respect  
4 to the compound case that we voiced previously wherein we  
5 believe that the polymorph case and the parties to it would be  
6 better served to have the compound case go first, and, you  
7 know, the parties are discussing that, but we're not informed  
8 yet as to where Chief Judge Wolfson is going with that trial.

9 And to the extent that there is some change in that  
10 schedule, you might be hearing from the parties. Obviously,  
11 we're not asking you to decide anything at the moment, but we  
12 do want to make you aware of that, that there may be some  
13 wrinkles in between the two cases that we may need to have the  
14 Court address.

15 THE COURT: What I would just ask is if there's any  
16 questions or issues to address regarding the scheduling of the  
17 trial, you should direct that correspondence to Judge Bumb,  
18 you could copy me on the letter, but Judge Bumb is going to  
19 decide all issues regarding trial scheduling, so she should  
20 get your letter.

21 MR. BATON: Absolutely, Your Honor. Thank you for  
22 that guidance.

23 THE COURT: And thank you all. I hope you all stay  
24 safe. You'll be hearing from the Court. We're adjourned.

25 Thank you again to the court reporter.

1           RESPONSE: Thank you, Your Honor.

2           (3:58 p.m.)

3           - - - - -

4

5           I certify that the foregoing is a correct transcript  
6 from the record of proceedings in the above-entitled matter.

7

8           /S/ Karen Friedlander, CRR, RMR  
9           Court Reporter/Transcriber

10          April 15, 2020  
11          Date

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